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09/490,019	01/21/2000	Mark L. Braunstein	16022-0101	6604

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EXAMINER

PATEL, JAGDISH

ART UNIT PAPER NUMBER

3624

DATE MAILED: 04/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/490,019

Applicant(s)

BRAUNSTEIN ET AL.

Examiner

JAGDISH PATEL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5,7,9-11,13,15-18,20 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1,2,5,7,9-11,13,15-18,20 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. This communication is in response to amendment filed 12/10/2003.

***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/10/04 has been entered.

***Claim Objections***

3. Claim 26 is objected due to the following informality.

"a health assistant" should read "the health assistant" for proper antecedent basis in the parent claim.

***Response to Amendment***

4. Applicant's amendment and accompanying supplemental declaration under 37 CFR 1.131 has overcome prior 35 USC 103(a) rejection of claims over Surwit et al.

5. Claims 1,2,5,7,9-11,13,15-18,20 and 23-25 have been amended and new claims 26 and 27 have been added per request.

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6. The pending claims have been examined and have been rejected over prior art of record.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1,2, 5, 7 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and dependent claims therefrom) recites step (from the remote computer,) sending to the health assistant an order modifying how the protocol treats the disease, this step does not positively relate to the step of receiving patient data collected by the health assistant.. and from the remote computer, sending to the health assistant an order modifying how the protocol treats the disease. This is because, the protocol is not modified in relation to the patient data collected by the health assistant.

Claim 2 is not sufficiently precise due to the combining of two different statutory classes of invention in a single claim.

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The preamble the claim refers to a method, but the body of the claim discusses the specifics of the system (remote computer).

Claims 9 and 10 pertain to limitation of the patient data collected by the health assistant. It is noted that this data do not functionally relate to the process steps of the independent claims. In other words, the configuring, receiving and sending steps of claim 1 are performed regardless of the attributes of the collected data. This defect renders, the limitation as reciting non-functional data. See *In re Gulack*, 217 USPQ 401 (CAFC 1983), ***language that is not functionally interrelated with the useful acts, structure, or properties of the claimed invention will not serve as a limitation.***

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 2 is rejected under 35 U.S.C. §101 because the claimed invention is directed to a non-statutory subject matter.

35 U.S.C. §101 requires that in order to be patentable the invention must be a "new and useful process, machine, manufacture or composition of matter or new and useful improvement thereof" (emphasis added). Applicant's claim mentioned above is intended to embrace or overlap two different statutory classes of invention as set forth in 35 U.S.C. §101. The claim begins by discussing a method (ex. Preamble of claim is directed to "the method), the body of the claim discusses the specifics of the system (limits the remote computer). "a claim

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of this type is precluded by express language of 35 U.S.C. §101 which is drafted so as to set forth statutory the statutory classes of invention in the alternative only", Ex parte Lyell (17USPQ2d 1548).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 5, 7 and 9-10 are rejected under 35

U.S.C. 102(b) as being anticipated by Brown (US Pat. 5,828,943)

(Brown).

Per claim 1, Brown discloses a method for delivering health care through a health assistant, (a compact microprocessor-based unit, see abstract) said method comprising:

providing a patient with a health assistant; (Fig . 1 microprocessor based unit..., see also pertinent description in col. 8 L 10+)

configuring the health assistant with a protocol comprising multimedia software content for treating a diseases of the patient .. ; (col. 8 L 10+ ..operation of microprocessor-based unit 10 for diagnostic assessment of physiological condition,

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..L 46+ microprocessor-based unit generates audio and video signals ..presented to the patient..)

at a computer remote from the health assistant, receiving patient data collected by health assistant in accordance with the protocol; (col. 9 L 39+ "remote exchange of data and information between a microprocessor-based unit 10 and either a remotely located clinician 16, or a clearinghouse 18. In such an arrangement, clearinghouse 18 includes one or more digital signal processors and associated peripheral equipment (e.g., printers, signal storage media, facsimile facilities) sufficient for gathering diagnostic measurement information from a relatively large number of microprocessor-based diagnostic tools (represented by microprocessor-based unit number 1 and microprocessor-based unit number 2 of FIG. 1)

from the remote computer sending to the health assistant an order modifying how the protocol treats the disease (col. 10 L 10+ "signals representative of information gathered during a diagnostic assessment procedure (and other signals appropriate to system operation) are coupled to (or from) clearinghouse 18 and microprocessor-based diagnostic unit 10 via a data management unit 28 and a communication link 30.")

Claim 2: remote computer is a server ..periodically accesses (refer to the central server ..Fig. 1).

Claim 5: sending the order from the remote computer to a server that is remotely accessible by the health assistant; (clearing house 18, and link 30 and link 20 which connects the health assistant (micro processor based unit #2) to clinician's computer 22);

Sending the order from the server to the health assistant (see link 30 which connects clearing house 18 to the micro processor based unit #2)

(for further description of the relevant to the claim refer to col. 10 L 10-39).

Claims 7 and 9: patient data collected by the health assistant..(col. 4 L 32+ "diagnostic assessment" and "assessment of the psychological condition of interest")

10. Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Fu et al (US Pat. 4,803,625).

Per claim 23 Fu discloses a computer-readable medium (home unit or remote unit comprising a main CPU 64) for storing ..instructions for performing the step of:

Reminding a patient to perform a task included in an order..during a first connection with a remote sever( the medication reminder event is flowcharted in FIG. 13, remote server is central unit 20);

Receiving form the patient an indication of a symptom ..( FIGS. 10 and 11 illustrate one important feature of



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this invention. The monitor collects a first set of test data (which in the example of FIG. 11 includes patient temperature), and then compares this first set of data with pre-selected test criteria. In the event the first set of data fail to correspond to the pre-selected test criteria, the monitor collects additional data (in the example of FIG. 11, data regarding blood pressure, fever symptoms and exercise patterns), all of which are stored in the composite log. These additional data assist trained medical personnel in interpreting the significance of the original data which failed to meet the test criteria. Thus, when the composite log is transmitted to the central unit, it provides information needed to diagnose the state of the patient..).

Sending notification of the symptom to the remote server during a second connection with the remote server .. (col. 4 L 44+ .. to communicate the results of the tests, the patient's answers to the questions, and medication compliance information to a central unit staffed with trained medical personnel..).

Claim 24 is analyzed in a manner of aforementioned description prior art presented in claim 23.

Claim 25. Fu discloses a health assistant system comprising:

A health assistant that is configured for periodically forming a communication connection with a remote server (see Fig. 1 and description at col. 5 L 44-52);

..receiving orders from a clinician for treating a patient; instructing the patient to perform tasks included in the orders;

collecting information from the patient about he symptoms..; and

sending information to the computer server over the communication network (col.4 L 44+ ..this monitor is designed (1) to prompt the patient to perform tests and to respond to questions as prescribed by a physician having responsibility for the care of the patient; (2) to prompt the patient to take medication as prescribed and to log compliance by the patient; and (3) to communicate the results of the tests, the patient's answers to the questions, and medication compliance information to a central unit staffed with trained medical personnel.).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown as applied to claim 1 and further in view of Fu.

Brown fails to teach receiving an alert at the remote computer that the patient data merits review by a clinician.

Fu, in the same field of endeavor, teaches a system and method for collecting data and managing patient care. Fu teaches receiving an alert signal associated with the patient data at the remote computer;

(abstract, The computer is also programmed to alert the central unit promptly in the event one or more measured parameters falls outside of a prescribed normal range.).

It would have been obvious, in view of Fu to one of ordinary skill in the art at the time of the application to implement communicating an alert at the remote computer because the alert would enable the patient to seek medical help in emergency situation.

12. Claims 11, 13, 15-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu et al (US Pat. 4,803,625) (Fu) and further in view of Brown (5,828,943) (Brown).

Per claim 11 Fu discloses a computer-implementable method for providing health care under the supervision of a remote clinician said method comprising:

Providing to a patient computer via a connection with a remote server, an order that is received from a clinician ;

(col. 1 L 47+ ..means are also provided ..selected messages  
..prescribed parameter schedule..prescribed medication schedule,  
patient computer is home unit 60 which includes CPU 64 connected to  
remote server (central unit 20), see description of "System Hardware"  
in col. 5)

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..transmitting from the patient computer to the remote server, an indication of a symptom experienced by the patient;

(col. 14 L 42+ .. log includes both information indicative of measured health parameters of the patient and information indicative of the schedule with which prescribed medication was actually taken by the patient. By providing trained personnel at the central unit with both types of information, the diagnostic value of the composite log is materially enhanced, also refer to Fig. 12 and pertinent description at col. 14 .. The preferred embodiment of the monitor of this invention cross-correlates multiple parameters in order to alert the central unit in the event of a potentially dangerous situation, while minimizing the number of false alarms.)

Fu fails to teach after the step of transmitting the indication of a symptom experienced by the patient, sending, from the remote server to a clinician computer, notification of symptoms so that a clinician can evaluate a need for a new order.

Brown, in the same field of endeavor discloses a computer-implantable method for providing health care under the supervision of a remote clinician (see Figure 1, abstract). Brown teaches transmitting patient data from a remote server (clearing house 18, described in col. 1 L 39+) to a clinician computer 16 (see col. 10 L 10-24 for communication link between the remote server 18 and the clinician's computer 16).

Therefore, in view of Brown it would have been obvious to one of ordinary skill in the art at the time of the application to enhance Fu method so the transmitting the indication of a symptom experienced by the patient, sending, from the remote server to a clinician computer, because communicating the patient data to a clinician at the clinician's computer would provide the clinician to promptly attend the patient thereby providing the needed assistance to the patient in a timely manner.

Per claim 13, Fu teaches..querying the patient to report the symptom and

as a result of said step of querying the patient to report the symptom, receiving the indication of the symptom from the patient.

(col. 2 L 7-15 ..By providing both information regarding physical condition of the patient and patient compliance with the medication schedule, this monitor materially assists medical personnel in assessing the health of the patient. As used herein, the term "health parameters" is intended in its broad sense to encompass both measurements of vital signs such as pulse, blood pressure, ECG and the like, as well as determination of patient symptoms by patient responses to questions. Col. 3 L 24-27, ..Of course, the first set of data can include data collected over an extended time period and indicative of a

trend or data collected in a single measurement or question and answer session.)

Claim 15: Fu fails to disclose the step of querying the patient to report the symptom comprises presenting multimedia information to the patient.

Brown, in the same field of endeavor discloses a computer-implantable method for providing health care under the supervision of a remote clinician (see Figure 1, abstract). Brown teaches using a multimedia information to collect symptoms of a disease of a patient. (col. 3 L 51-65, video signals interactively prompt a patient to operate one or more switches ..also includes a second sound generator..appropriate to the video display during the operation of the microprocessor-based unit).

Therefore, in view of Brown it would have been obvious to one of ordinary skill in the art at the time of the application to enhance Fu method such that the querying the patient incorporate multimedia information. Motivation for presenting information and in particular queries to the patient in a multimedia format is that the queries are easily comprehended by the patient and involves the patient in their own care.

Claims 16 and 17: Fu teaches querying the patient to determine whether the patient has completed a task associated

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with the order ..notifying the remote server whether the patient has completed the task associated with the order (col. 1 L 68+ records patient compliance with the prescribed medication).

Claim 20. Fu teaches ..allowing a user to input the indication of a symptom experienced by the patient via a touch screen interface (refer to SYSTEM HARDWARE L 61+ ..Of course, other I/O devices can be included as well, such as touch screens, microphones, and the like.

14. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fu as applied to claim 11 and further in view of Brown (US 6032119) (Brown '119).

Fu as analyzed above fails to teach providing the patient with education material about diseases of the patient.

Brown '119, in the same field of endeavor discloses a computer-implantable method for providing health care. Brown teaches providing the patient with education material about diseases of the patient (see "Background of the Invention" .. Preventive care includes educating patients about their disease, ensuring communication between patients and health care providers (e.g. doctors), and providing patients with tools and/or treatments for managing their disease.).



Therefore, in view of Brown it would have been obvious to one of ordinary skill in the art at the time of the application to enhance Fu by providing the patient with educational material about a disease because providing education about a diseases would enable to take preventive care to maintain good health and habits.

15. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fu as applied to claim 25 and further in view of Brown (US 5828943) (Brown.)

Claim 26. Fu as discussed in analysis of claim 25 fails to disclose, however, Brown teaches a clinician computer configured for receiving orders from the clinician and sending the orders to a health assistant via the server. (Brown col. 10 L 10-39, refer to communication links 30, 34 and 20, linking the health assistant with the clinician computer 22 via the clearing house 18)

Therefore, in view of Brown it would have been obvious to one of ordinary skill in the art at the time of the application to enhance Fu by providing a clinician computer as discussed above. Motivation for this improvement is that it would facilitate direct and efficient communication of the clinician's order to the patient's health assistant for prompt care.

Regarding claim 27, Fu in combination with Brown discloses the functions of sending an alert signal as recited being carried out by the health assistant itself (..abstract "The computer is also programmed to alert the central unit promptly in the event one or more measured parameters falls outside of a prescribed normal range." ).

However, Fu or Brown do not teach that the alert function is performed at the clinician computer. However, it is noted that rearranging the elements of an apparatus to achieve same functionality is well within scope of ordinary skill of those artisan developing such apparatus. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have the clinical computer configured for sending an alert to the clinician as per claim and as disclosed by combination of references cited above because it would still achieve same functionality.

#### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagdish Patel whose telephone number is (703) 308-7837. The examiner can normally be reached Monday-Thursday from 8:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vincent Millin, can be

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reached at (703) 308-1038. The fax number for Formal or Official  
faxes to Technology Center 3600 is (703) 305-7687. **Draft faxes  
may be submitted directly to the examiner at (703) 746-5563.**

Any inquiry of a general nature or relating to the status  
of this application should be directed to the Group receptionist  
whose telephone number is (703) 308-1113 or 308-1114. Address  
for hand delivery is 2451 Crystal Drive, Crystal Park 5, 7<sup>th</sup>  
Floor, Alexandria VA 22202.



Jagdish N. Patel

(Primary Examiner, AU 3624)

4/19/04